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7 Inc., a New York corporation; FUJIFILM Corporation, a
Japanese Corporation; and GE HEALTHCARE INC.,
8 a Delaware corporation.

9 UNITED STATES DISTRICT COURT
10 SOUTHERN DISTRICT OF CALIFORNIA
11

12 ANTICANCER, INC., a California
corporation,

13 Plaintiff,

14 v.
15

16 FUJIFILM MEDICAL SYSTEMS U.S.A.,
INC., d/b/a FUJIFILM LIFE SCIENCE, a
New York corporation; FUJIFILM
17 CORPORATION, a Japanese Corporation;
GE HEALTHCARE INC., a Delaware
18 corporation; and DOES 1-100,

19 Defendants.
20

21 AND RELATED COUNTERCLAIM.
22

Case No. 09-CV-1311-AJB (JMA)

**RESPONSIVE CLAIM CONSTRUCTION
BRIEF OF DEFENDANTS AND
COUNTERCLAIM PLAINTIFFS
FUJIFILM MEDICAL SYSTEMS U.S.A.,
INC., d/b/a FUJIFILM LIFE SCIENCE;
FUJIFILM CORPORATION; AND GE
HEALTHCARE INC.**

Judge: Honorable Anthony J. Battaglia
Courtroom: 4
Date: April 8, 2011
Time: 9:30 A.M.
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I. INTRODUCTION

In arguing for its proposed constructions, AntiCancer flaunts the law guiding construction of claim terms and ignores the facts by:

- ignoring the intrinsic evidence from the '038 patent and '159 patent claims, specification and prosecution history;
- urging claim constructions inconsistent with AntiCancer's own proffered intrinsic and extrinsic evidence;
- improperly attempting to limit claims terms to preferred embodiments;
- arguing that Defendants are not entitled to advance the plain and ordinary meaning for a claim term;
- relying on claim constructions reached in a prior action having no collateral effect on this action; and
- in many instances, simply inventing constructions out of whole cloth without any proffered support whatsoever.

In contrast, Defendants Fujifilm Medical Systems U.S.A. Inc., Fujifilm Corporation (collectively Fujifilm), and GE Healthcare Inc. (GE Healthcare) construe the claim terms based on *verbatim* support from the specifications of the asserted patents, express disclaimers from the prosecution history, and unambiguous extrinsic evidence. Accordingly, AntiCancer's constructions should be rejected and Defendants' constructions adopted.¹

II. NO WAIVER ATTACHES TO DEFENDANTS' PROPOSAL THAT CERTAIN TERMS SHOULD BE GIVEN THEIR PLAIN AND ORDINARY MEANING

For a few disputed terms, Defendants propose adoption of the plain and ordinary meaning with no additional construction required beyond the construction of individual terms within those phrases as proposed by Defendants. AntiCancer incorrectly contends that in so doing, Defendants somehow waived their rights for construing these disputed phrases.

It not only is proper but indeed common for a party to argue that a claim term/phrase should be interpreted according to its plain and ordinary meaning without the need for construction by the court. Taking such a position is neither a "waiver" nor an acceptance of the

¹ In its opening claim construction brief, AntiCancer gratuitously provides a blatantly biased description of Defendants' businesses and Defendants' alleged misconduct, particularly as it relates to the accused products. While Defendants dispute AntiCancer's characterizations, Defendants choose not to respond to those allegations here as they are irrelevant to claim construction. Claims should not be construed by reference to the accused device. *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002) (citing *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985)).

opposing party's proffered construction. In fact, it is black letter law that words in a claim should be given their plain and ordinary meaning where possible. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) ("We have frequently stated that the words of a claim "are generally given their ordinary and customary meaning.") (internal citations omitted).

Hence, courts have routinely held that certain terms need no construction. *See Websidestory, Inc. v. Netratings, Inc.*, Case No. 06CV408 WQH (AJB), 2007 U.S. Dist. LEXIS 50186, *10-28 (S.D. Cal. July 10, 2007) (holding that ten terms being considered by the court require no construction). When the ordinary meaning of the term speaks for itself, the Court should avoid paraphrasing the language. *Pagemelding, Inc. v. Feeva Tech., Inc.*, Case No. C08-03484 CRB, 2009 U.S. Dist. LEXIS 80886, 26-27 (N.D. Cal. Aug. 19, 2009). Indeed, AntiCancer cites authority supporting this very principle. *Broadcom Corp. v. Qualcomm Inc.*, Case No. 05-467-JVS (RNBX), 2006 U.S. Dist. LEXIS 97882 at *85-6 (C.D. Cal. Sept. 11, 2006) (Qualcomm proffered constructions of "length," "frequency," and "spreading code," Broadcom argued these terms needed no construction, and the Court agreed) (not challenged on appeal).

Because the terms for which Defendants urge adoption of their plain and ordinary meaning are unambiguous and fully understandable in ordinary English and derive no special meaning from the patents-in-suit, their plain and ordinary meaning should be adopted, without construction by the Court.

III. ANTICANCER'S PROPOSED CONSTRUCTIONS BASED SOLELY ON A PRIOR CASE'S CLAIM CONSTRUCTION ORDER THAT LACKS COLLATERAL ESTOPPEL EFFECT SHOULD BE REJECTED

AntiCancer agrees that the claim construction order on which it bases many of its proposed constructions (the *CRI* Order, as described in Defendants' Opening Claim Construction Brief ("Defendants' Opening Brief")) has no collateral effect in this action. *See* Dkt. 72, at 4 n. 2. However, AntiCancer then turns around and urges the selective adoption of claim constructions from the *CRI* Order – of the nine disputed terms in this case that overlap with the *CRI* case, AntiCancer asks this Court to adopt the constructions for five of the terms, while disregarding the *CRI* court's constructions of the remaining four.² Because the *CRI* Order is not a proper basis for

² The four terms for which AntiCancer urges the Court to adopt a construction differing from

1 construing these disputed terms, the *CRI* Order constructions should be disregarded when
 2 construing the disputed terms in the present case between AntiCancer and Defendants.

3 **IV. THE COURT SHOULD ADOPT DEFENDANTS' PROPOSED CLAIM**
 4 **CONSTRUCTIONS**

5 AntiCancer identifies four disputed terms and phrases in the '159 patent and 16 in the
 6 '038 patent. AntiCancer admits that these disputes center on the terms that Defendants discuss
 7 below. *See, e.g.*, Dkt. 72, at 13, 19, 20, and 21.

8 **A. Disputed Terms/Phrases in the '038 Patent**

9 **1. "metastasis"**

10 Defendants' proposed claim construction, "the growth of secondary tumors from the
 11 primary tumor at sites different from the primary tumor," is taken *verbatim* from the specification
 12 of the '038 patent. AntiCancer's construction, by contrast, relies on a combination of incomplete
 13 bits from the specification, misinterpreted extrinsic evidence, and its own version of "common
 14 sense." Dkt. 72, 15-17.

15 AntiCancer's Opening Claim Construction Brief cites two passages from the '038
 16 specification as support for its assertion that "[t]he specification accords with AntiCancer's
 17 broader definition." Dkt. 72, at 15. However, nothing in the passages cited by AntiCancer
 18 supports a definition broader than that provided in the '038 specification (relied upon by
 19 Defendants). Instead, those two passages address the *mechanism* of metastasis; they do not *define*
 20 metastasis nor *expand* the explicit definition in the '038 specification. Indeed, one of the
 21 passages AntiCancer cites specifically supports Defendants' proposed construction (including the
 22 growth of a secondary tumor), repeatedly mentioning the ability to understand metastasis through
 23 observing "secondary tumor emboli," and stating that the "growth of secondary tumor" is

24
 25 those adopted in the *CRI* order are "Whole-body external fluorescent optical imaging,"
 26 "metastasis," "metastasize," and "fluorescent optical tumor imaging." Dkt. 72, at 12. In
 27 AntiCancer's earlier-filed opening claim construction brief, AntiCancer only asked the Court to
 28 adopt a different construction for "whole-body external fluorescent optical imaging." Dkt. 49, at
 21. On a related matter, one of the two opening claim construction briefs that AntiCancer filed in
 this case should be stricken from the record. Allowing AntiCancer to twice present its arguments
 on claim construction, first, in its May 2010 brief (Dkt. 49) and now again in its March 2011 brief
 (Dkt. 72), would give AntiCancer an unfair advantage and prejudice Defendants.

1 “crucial” in understanding the mechanism of “metastasis.” Dkt. 72, at 16. Thus, even
2 AntiCancer’s cited specification supports Defendants’ proposed claim construction.

3 Further, nothing in those passages indicates that the ’038 patent’s express definition of
4 “metastasis” (*i.e.*, Defendants’ proposed construction) is ambiguous or that the word “metastasis”
5 is used inconsistently within the ’038 patents. Without such a showing, it is improper for
6 AntiCancer to rely upon extrinsic evidence, *i.e.*, a dictionary definition, to modify the clear
7 definition of “metastasis” in the specification. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d
8 1576, 1584 (Fed. Cir. 1996) (“Only if there [is] still some genuine ambiguity in the claims, after
9 consideration of all available intrinsic evidence, should the trial court[] resort[] to extrinsic
10 evidence”). Indeed, as explained in Defendants’ Opening Brief, the extrinsic evidence cited by
11 AntiCancer in fact supports Defendants’ proposed construction.³

12 Finally, AntiCancer purports to rely on “common sense” for its construction. However,
13 the ’038 patent provides a specific definition for the term which should not be cavalierly
14 overridden; it is settled law that the patentee is entitled to be his own lexicographer. *Phillips*, 415
15 F.3d at 1316. Further, the so-called “common sense” argument advanced by AntiCancer (that
16 metastasis may encompass “spreading of cancer/tumors at sites different from the primary tumor”
17 (*see, e.g.*, Dkt. 69, at 11)) is harmonious with the appearance of secondary tumors;⁴ obviously,
18 secondary tumors cannot grow without such “spreading.” But that does not mean metastasis as
19 defined by the patentee occurs in the absence of secondary tumors.

20 Thus, the Court should adopt Defendants’ construction.

21 2. **“administering said protocol or drug to a subject which is a mouse,**
22 **rat or rabbit which contains a primary tumor that stably expresses**
23 **green fluorescent protein (GFP) in cells of said tumor when said**
24 **tumor metastasizes”**

25 ³ Specifically, AntiCancer cites the definition of metastasis from the Merriam Webster’s
26 Collegiate Dictionary. Dkt. 72, at 16. The second definition in the dictionary defines metastasis
as a **secondary metastasis** growth of a malignant tumor. Dkt. 72 Ex. 3, Merriam Webster’s
27 Collegiate Dictionary 10th Ed. at 731 (emphasis added).

28 ⁴ This principle is supported by the case AntiCancer relies on for its “common sense” approach.
In *Lisle Corp. v. A.J. Mfg. Co.*, the court relied on the “patent specification” to “attain a common-
sense meaning of [the] claim limitation,” not just on “common sense.” 398 F.3d 1306, 1314 (Fed.
Cir. 2005).

AntiCancer fails to offer any reason for diverging from Defendants' proposed construction for the above-cited phrase. Without citation to any intrinsic or extrinsic support, Anticancer adds "consistently" to modify the verb "express." All that AntiCancer offers by way of explanation for its addition is that "consistently" is synonymous with "stably." Dkt. 72, at 17. Such addition is unnecessary (and improper) surplusage, as explained in Defendants' Opening Brief (Dkt. 71, at 11-12), and should therefore be rejected in favor of Defendants' construction.⁵

3. **"a primary tumor that stably expresses green fluorescent protein (GFP) in cells of said tumor when said tumor metastasizes"**

While Defendants rely on intrinsic and extrinsic support for construction of the above phrase, AntiCancer's proposed claim construction relies on neither. Instead, AntiCancer improperly relies on the construction from a prior case to which collateral estoppel does not attach. Dkt. 72, at 18-19. Further, AntiCancer attempts to refute Defendants' proposed claim construction (*see* Dkt. 71, at 9) by making arguments based neither on law or fact. First, AntiCancer argues that because the word "phenotype" is not used in the specification, it cannot be used to construe the claim. However, AntiCancer cites no legal authority to support such assertion, and Defendants are aware of none. Second, AntiCancer argues that use of the phrase "cell lines" causes confusion. But this is factually contradicted by the specification and the claim language. Dkt. 71, at 10-11. Hence, Defendants' construction should be adopted.

4. **"green fluorescent protein (GFP)"**

In order to advance its proposed construction for GFP, Anticancer resorts to mischaracterizing Defendants' claim construction. AntiCancer states that Defendants hold the position that GFP cannot "exhibit colors other than green" (Dkt. 72, at 18-9) when in fact Defendants' position is that GFP, as used in the '038 patent, includes proteins that fluoresce only green in their natural state. As explained in Defendants' Opening Brief, there is no support in the claim language to expand the definition of GFP to cover *unmodified* proteins that naturally fluoresce in colors other than green, such as native blue fluorescent proteins (BFPs) or native red fluorescent proteins (RFPs). On the other hand, there is strong intrinsic evidence that GFP is

⁵ Another dispute is related to whether the drug or protocol is given to a first mouse, as advanced by AntiCancer, or a mouse, as Defendants propose. Defendants' position is fully explained in Defendants' Opening Brief. Dkt. 71, at 12.

1 limited to a protein that fluoresces green *in its natural state* (while man-made GFP mutants
2 encompass mutants that fluoresce in additional colors). Since Defendants' construction is
3 consistent with the intrinsic evidence and should be adopted.

4 **5. "control subject"**

5 In contesting Defendants' proposed construction for "control subject", AntiCancer again
6 eschews citation to intrinsic and extrinsic evidence and simply asserts that "control animal is
7 never the same actual animal as the subject animal." By contrast, in support of their construction,
8 Defendants cite strong extrinsic evidence that the control animal can be the same animal as the
9 treatment animal. Because there is insufficient intrinsic evidence to ascertain the meaning of
10 "control animal," such reliance is appropriate. *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082,
11 1090 (Fed. Cir. 2003). Therefore, this construction should be adopted.

12 **6. "genetically immunocompromised"**

13 The primary difference between the parties' proposed claim constructions with respect to
14 the phrase "genetically immunocompromised" is whether the term can be applied with respect to
15 subjects which are immunocompromised by irradiation or from receiving immunosuppressants
16 (neither of which results from a genetic defect). AntiCancer claims that its claim construction
17 accords "most closely with the specification" because the specification contains the exemplary
18 phrase "such as Nude and SCID mice." However, the scope of Defendants' proposed claim
19 construction also would include Nude Mice and SCID mice. Defendants' claim construction
20 further is mandated by the prosecution history of the '038 patent. As Defendants explained in
21 detail in their Opening Claim Construction Brief, the patent examiner repeatedly refused to allow
22 claims which covered all ways of being "immunocompromised," especially subjects
23 immunocompromised by irradiation or by providing immunosuppressants on the ground that such
24 broad claims were not enabled. *See, e.g.*, Dkt. 71-1, at 91. Instead, the examiner insisted that
25 AntiCancer amend its claims and limit them to "genetically immunocompromised," despite the
26 declaration and video evidence AntiCancer submitted. Thus, the claims must be interpreted in
27 accordance with this limitation. *See, e.g., Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314,
28

1323 (Fed. Cir. 2003) (The doctrine of prosecution disclaimer ... preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution).

In proposing the construction of a related term “immunocompromised” in the phrase, “wherein said control subject contains said tumor that expresses GFP, wherein said control subject is an **immunocompromised** mouse, rat or rabbit, or a mouse, rat or rabbit which is syngeneic to said tumor,” AntiCancer attempts to further broaden the construction of the above phrase to include impaired immune systems *caused by any reason*. Again, this construction is directly at odds with the prosecution history because it attempts to expressly limit the phrase “genetically immunocompromised” to embodiments *other* than those caused by a genetic defect. While AntiCancer claims that Defendants’ claim construction “varies from Judge Sammartino’s definition of the same term [in the *CRI* case]” (Dkt. 72, at 22), it is AntiCancer’s claim construction, not that of the Defendants, that varies significantly from Judge Sammartino’s claim construction of “having an inherited genetic defect.” Accordingly, Defendants’ construction, and not AntiCancer’s, should be adopted.

7. “intact”

The source of Defendants’ proposed definition for “intact” is cited on the face of the ’038 patent and also is discussed in the ’038 prosecution history. Dkt. 71-1, at 6, 109-110. AntiCancer attempts to counter this clear intrinsic evidence only by stating that “Defendants’ construction omits the word ‘opening,’ which is a word the specification uses repeatedly in context.” Dkt. 72, at 20. Even if this argument were sufficient to rebut the strong intrinsic support for Defendants’ proposed construction, it is simply wrong. Defendants relied upon many places in the specification that use the word “opening” to construe “intact.” For example:

The monitoring can occur **either on the whole vertebrate by opening the animal and observing the organs directly with a fluorescent microscope**, or the tissues may be excised and examined microscopically.

Dkt. 71-1, at 11, col. 5, lns. 27-31 (emphasis added).

..., the abdominal cavity **opened** sufficiently to visualize the tumor.

Dkt. 71-1, at 14, col. 12, lns. 15-16 (emphasis added).

Thus, AntiCancer's Proposed Construction, "subject **without** any surgical openings in the skin," *is directly contrary to* the intrinsic evidence. Dkt. 69, at 21-22 (emphasis added). Even the two sections of the specification that Anticancer cites for the first time in its Opening Claim Construction brief support Defendants' proposed construction⁶:

In some cases the tumors are sufficiently bright that opening the animal is unnecessary—they can be seen directly through the skin.

Dkt. 71-1, at 11, col. 5, ln. 33 (emphasis added).

In some cases, abdominal opening is unnecessary as the intraperitoneal tumors can be visualized through intact skin.

Dkt. 71-1, at 14, col. 12, ln. 18. (emphasis added).

These passages, then, only indicate that "in some cases" subjects can be observed without "openings in the skin." These are just two examples, and as such should not be used to limit the claims. *See Comark Comm. v. Harris Corp.*, 156 F.3d 1182, 1186 (cautioning "against limiting the claimed invention to preferred embodiments or specific examples in the specification.") Defendants' broader construction includes such embodiments.

Because Defendants' proposed claim construction is directly supported by the strong and unrefuted intrinsic evidence, including the same and only intrinsic evidence that AntiCancer relies on, the Court should adopt Defendants' proposed construction.

8. "fluorescent optical tumor imaging"(FOTI)

Defendants' proposed claim construction is taken again *verbatim* from the specification. Dkt. 71-1, at 11, col. 5, lns. 42-55. AntiCancer cites this same paragraph in the specification but provides no explanation as to how it supports AntiCancer's construction.

In contesting the Defendants' proposed construction, AntiCancer contends that Defendants' proposed construction is "overly broad" and "imprecise." However, it is AntiCancer's proposed claim construction that is "overly broad" and "imprecise." Dkt. 72, at 24. As it is clearly supported by the specification, the FOTI is limited to observing metastasis. *See, also*, Dkt. 71-1, at 14, col. 12, 63-65 (emphasis added).

⁶ Here, AntiCancer's Opening Brief improperly relies on citations not identified by AntiCancer in the Joint Claim Construction Chart Support Chart, Dkt. 69, even though such identification is required under the Patent Local Rules.

Defendants' proposal. Administering nucleic acid directly into the body of the animal is a way of "delivering, to an animal, cells containing a nucleic acid encoding a flurophore" because such delivering procedure will result in cells containing a nucleic acid encoding a flurophore in the tested animal. Accordingly, the Court should adopt Defendants' proposed claim construction.

3. "whole-body external fluorescent optical imaging"

Defendants' proposed construction relies on *verbatim* support in the specification for its definition. *See* Dkt. 71-1, at 23, col. 5, lns. 60-66. While AntiCancer states that its definition is "a concise and faithful paraphrase of the specification," Dkt. 72, at 12, AntiCancer also improperly attempts to add the limitation "in real time and on a continuous basis." Dkt. 69, at 5. In support of its construction, AntiCancer directs the Court to passages from the specification that contain the language of "real time" or "continuous." But these citations only show that "whole-body external fluorescent optical imaging" "affords" real time or continuous observation; it does not support that "whole-body external fluorescent optical imaging" is *limited* to "real time and on a continuous basis." *See, e.g., Power Mosfet Tech., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1407-9 (Fed. Cir. 2004) (discussing the difference between "permitting," which is non-limiting, vs. "requiring," which is limiting); *Comark Comm.*, 156 F.3d at 1186. The specification clearly states that the image can be "captured directly on an IBM PC **or continuously** through video output." Thus, whole-body external fluorescent optical imaging does not have to be conducted continuously for every embodiment. Dkt. 71-1, at 31, col. 22, lns. 56-60 (emphasis added). Accordingly, Defendants' proposed construction should be adopted.⁷

V. CONCLUSION

For all the foregoing reasons, Defendants respectfully request that the Court enter an order adopting Defendants' proposed claim construction for the patents-in-suit.

⁷ AntiCancer misrepresents Defendants' proposed claim construction in stating that the Defendants proposed construction includes the language "whether or not the organism is unrestrained and mobile" in their proposed construction; it does not. Dkt. 71, at 21-22.

1 Dated: March 22, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I am a citizen of the United States, more than eighteen years old and not a party to this action. My business address and place of employment is Orrick, Herrington & Sutcliffe LLP, 1152 15th Street, Washington, DC 20005.

I hereby certify that, on March 22, 2011, I have taken steps to cause this document, **RESPONSIVE CLAIM CONSTRUCTION BRIEF OF DEFENDANTS AND COUNTERCLAIM PLAINTIFFS FUJIFILM MEDICAL SYSTEMS U.S.A., INC. d/b/a FUJIFILM LIFE SCIENCE; FUJIFILM CORPORATION; AND GE HEALTHCARE INC.**, to be sent to the registered participants as identified on the Notice of Electronic Filing (“NEF”), including the following:

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Executed on March 22, 2011, at Washington, DC.

Respectfully submitted,

By:


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